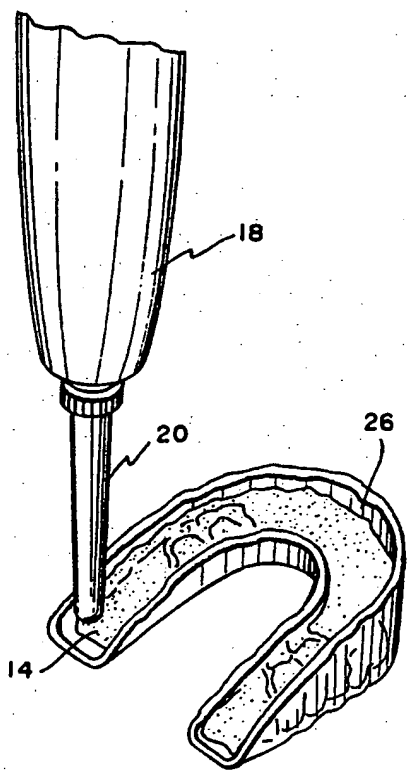




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61C 7/00	A1	(11) International Publication Number: WO 92/02190 (43) International Publication Date: 20 February 1992 (20.02.92)
(21) International Application Number: PCT/US91/05556 (22) International Filing Date: 9 August 1991 (09.08.91) (30) Priority data: 564,753 9 August 1990 (09.08.90) US (71)(72) Applicant and Inventor: SILVERMAN, Harvey, N. [US/US]; 3406 Kersdale Road, Pepper Pile, OH 44124 (US). (74) Agent: DE LEON, Josefino, P.; Shlesinger, Arkwright & Garvey, 3000 South Eads Street, Arlington, VA 22022 (US).		(81) Designated States: AT (European patent), AU, BB, BE (European patent), BR, CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, PL, RO, SE (European patent), SU. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: METHOD AND SYSTEM FOR WHITENING TEETH (57) Abstract A method for whitening the teeth of a person, comprises the steps of a retainer (2) made of a plastic material adapted to be moldable when heated for conforming to the shape of one of the upper and lower teeth of the person; heating the retainer (2) until soft and moldable without losing its basic shape; fitting the retainer (2) around one of the upper and lower teeth; applying a layer of tooth whitening composition (14) inside the retainer; wearing the loaded retainer (2) for several hours each day until the teeth to be whitened have become whiter; replacing the tooth whitening composition every 1-2 hours; and repeating the above steps with another retainer for the other of lower and upper teeth. 		

+ DESIGNATIONS OF "SU"

It is not yet known for which States of the former Soviet Union any designation of the Soviet Union has effect.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU ⁺	Soviet Union
CM	Cameroon	LJ	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

-1-

METHOD AND SYSTEM FOR WHITENING TEETHFIELD OF THE INVENTION

5 The present invention relates generally to
dental treatment and more particularly to a method
and system for applying tooth whitening composition
to a person's teeth.

BACKGROUND OF THE INVENTION

10 Many commercially available toothpastes remove
stains through abrasives, which can damage the tooth
enamel. Toothpastes are unable to whiten teeth that
are naturally yellow or gray in color. The present

-2-

method of obtaining whiter teeth includes tooth bonding, capping or in-office dental bleaching procedures. These methods are relatively costly and therefore not widely available to everyone.

5 The in-office dental bleaching procedure involves making an alginate impression of the arch to be treated. From the resultant hydrocal cast, a vacuum-formed soft plastic night guard, approximately 2 mm thick, is fabricated. The custom
10 made tray is then used to apply a tooth whitening substance to the teeth to be whitened. The in-office procedure is fairly expensive and therefore not readily available to the consumers.

 Tooth whitening substances are currently
15 available in the market. A 10% Carbamide Peroxide, also known as perhydrol-urea, hydrogen peroxide carbamide, urea peroxide, or urea hydrogen peroxide, has been recommended for bleaching teeth. Prior use
20 of the chemical by dental clinics has been as oral antiseptic where tooth bleaching was a side effect of extended contact time. However, application of the substance involves using a cotton tipped applicator or a toothbrush, which does not make it
25 possible for the tooth whitening composition to stay in contact with the tooth for a longer period.

-3-

There is therefore a need to provide an apparatus and method for whitening teeth that is fairly inexpensive without requiring a visit to a dentist, that can be used effectively at home and that permits the tooth whitening composition to remain in contact with the teeth to be whitened for a relatively longer period of time.

OBJECTS AND SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a method and system for tooth whitening where the tooth whitening substance is permitted to remain in contact with the tooth to be whitened for a relatively longer period of time.

It is another object of the present invention to provide a method and system for tooth whitening where the tooth whitening substance can be applied at home, without requiring a visit to a dentist.

It is still another object of the present invention to provide a method and system for tooth whitening where the tooth whitening substance is carried in a tray which is custom fitted by a user to his teeth at home without a visit to a dentist.

In summary, the present invention provides a method and system for tooth whitening that is relatively inexpensive and permits the tooth

-4-

whitening substance to remain in contact with the teeth to be whitened for a relatively longer period of time.

These and other objects of the present invention will become apparent from the following detailed description.

BRIEF DESCRIPTIONS OF THE DRAWINGS

Figure 1 is a top perspective view of a retainer used in the present invention, shown before being custom fitted to a user's teeth.

Figure 2 is a side elevational view of the retainer of Figure 1, with portion broken away, shown being custom fitted to a user's upper teeth in accordance with the present invention.

Figure 3 is a top perspective view of a custom fitted retainer according to the present invention.

Figure 4 is a top perspective view of the custom fitted retainer of Figure 3, shown with the attached strap removed and shown with a layer of tooth whitening composition being applied therein in accordance with the present invention.

Figure 5 is a top plan view of the retainer of Figure 4 after the application of the tooth whitening composition.

-5-

Figure 6 is a top perspective view of a storage case for the custom fitted retainer of Figure 3 with the strap removed.

DETAILED DESCRIPTION OF THE INVENTION

5 A retainer 2 prior to being custom fitted to a user's upper or lower teeth according to the present invention is disclosed in Figure 1. The retainer 2 is substantially U-shaped in plan view and in cross-section. The retainer 2 is preferably made of
10 tasteless, non-toxic, yieldable, soft, plastic material, such as polyethylene obtainable from Brimms, Inc., Buffalo, New York. The retainer 2 becomes soft and moldable when heated so that it can be fitted and molded around the contours of the
15 upper or lower teeth of a user. The retainer 2 has a frontal bite portion 4 and a pair of leg portions 6 extending rearwardly thereof. The retainer 2 includes a bottom wall 8 connected to an inner retaining wall 10 and an outer retaining wall 12 to
20 form a trough 13 for receiving a tooth whitening composition 14, preferably in a gel, as best shown in Figure 2. A strap 16 is secured to the retainer 2.

25 The retainer 2 is similar in initial appearance to a mouth guard, such as disclosed in U.S. Patent

-6-

3,073,300, which is hereby incorporated by reference. However, the patent does not show the attached strap 16.

5 A squeeze tube 18 and a nozzle 20 threadedly secured thereto are preferably used to dispense the tooth whitening composition 14. The tooth whitening composition comprises an active ingredient of 10% Carbamide Peroxide (10%), EDTA disodium, citric acid, Carbopol 940, Triethanolamine, glycerin, and
10 flavors. The EDTA disodium and citric acid provide buffering agents and preservatives to maintain taste and effectiveness of the composition 14. The Carbopol 940, Triethanolamine and glycerin form the media in which the ingredients are contained. The
15 composition is preferably relatively much thicker, thereby allowing for less occurrence of seepage in the back of the throat. Although the ingredients of the composition 14 are not harmful to the body even if ingested, the consumer must refrain from
20 swallowing the composition 14 during use. A composition similar to the tooth whitening composition 14 is disclosed in U.S. Patent 3,657,413, which is hereby incorporated by reference. Several similar products are presently
25 available in the market.

-7-

A plastic case 22 is used to keep the retainer 2 when not in use.

OPERATION OF HOME USE AND APPLICATION

5 The kit supplied to the consumer includes a pair of retainers 2 for the upper and lower teeth, a tube 18 containing tooth whitening composition 14, a dispensing nozzle 20, and a carrying case 22, preferably one for each of the retainer 2. To use the kit, the retainer 2 is first custom fitted to the person's teeth in a series of steps described below.

15 A pot of water is brought to a full boil at 212 degrees F. The water is then allowed to sit until it stops boiling. Substantially immediately subsequent to the stopping of the boiling of the water, the retainer 2 is then held by the end of the strap 16 and placed entirely in the hot water and waved back and forth for approximately 5 seconds at substantially sea level. A person of ordinary skill in the art will understand that less immersion time may be required at higher altitudes because of the reduced boiling temperature of water. It is critical that accurate timing be observed. If the retainer 2 is under hot water too long, the material

-8-

will adhere to itself or lose its basic configuration.

After about at least 5 seconds, the retainer 2 is removed from the hot water and excess water is shaken off. The retainer 2 is then placed immediately around either the upper or lower teeth, centering it around the teeth, as best shown in Figure 2. The retainer 2 will be warm, but will not burn, since it quickly cools as soon as it is removed from the hot water. The retainer 2 preferably is approximately 0.09 inch thick at the base wall 8 and approximately 0.078 inch thick at the walls 10 and 12 so that it will readily become soft and moldable in a relatively short time and to provide for a comfortable wear.

Without delay, the upper and lower teeth are brought together, biting into the retainer 2; the tongue is pressed against the back of the upper teeth and any air and water from the retainer 2 is sucked out; and the fingers are used to mold the retainer 2 around the upper teeth to make a smooth tight fit, making sure that all of the teeth are covered. A mirror is preferably used for best results. It is important that the upper and lower

-9-

teeth be brought together and the procedure followed strictly at all times during the forming process in order to properly shape the retainer 2 to the contour of the teeth and gums.

5 If a good fit is not obtained, the above procedure may be repeated as many times as necessary, provided that the retainer 2 is not kept under hot water longer than five seconds each time.

10 The retainer 2 is then left in the mouth for approximately 30 seconds and then removed and placed under cold water to retain its new shape. The custom fitted retainer 2 attains teeth impressions 24 after being molded to the shape of the person's teeth, as best shown in Figure 3. The custom fitter
15 retainer 2 is then tried for comfort. When a good fit is determined, the strap 16 is trimmed with scissors.

20 All of the upper or lower teeth should be covered by the custom fitted retainer 2. For more comfortable fit or if too much of the gums are covered, the custom fitted retainer 2 may be trimmed with scissors.

-10-

The retainer 2 for the other of the lower and upper teeth is fitted in the same way as discussed above.

5 A very thin layer of the tooth whitening composition 14 is then placed on the inside surfaces of the trough 13 of the custom fitted retainer 2, as best shown in Figure 4. Preferably, a very thin layer 28 of the tooth whitening composition 14 is applied to the inside surface 26 of the outer wall 6
10 of the custom fitted retainer 2 such that the composition 14 will be applied to the front surfaces of the teeth to be whitened, as best shown in Figures 4 and 5. The tooth whitening composition 14 is used sparingly so that the minimum amount of
15 composition oozes out of the custom fitted retainer 2 when placed around the teeth.

The teeth to be whitened should be brushed before the loaded custom fitted retainer 2 is worn. The custom fitted retainer 2 with the tooth
20 whitening composition 14 is then seated completely and firmly over the teeth. The fingers are used so that the composition 14 covers the surface of the

-11-

teeth to be whitened. Any excess composition is removed with a facial tissue.

The custom fitted retainer 2 is worn approximately 5 to 18 hours per day. The tooth whitening composition 14 is preferably replaced every 1 1/2 hours. The rate of the whitening process is directly related to the period of use of the custom fitted retainer 2 and the frequency of change of the whitening composition 14. The more the custom fitted retainer 2 is used and the more often the whitening composition is replaced, the faster the whitening process proceeds. If the custom fitted retainer 2 is worn for a good part of the day, the desired color change will occur within one to two weeks. If it is worn for only a few hours daily, the process may take longer. Night time only users sometimes require a little more time to achieve maximum benefits, since the whitening composition 14 is not replaced during sleep.

It is recommended that the user does not wear both custom fitted retainers at the same time. It is also recommended that the consumer use the kit with one of the upper and lower teeth, preferably

-12-

the upper teeth, until the desired color change is achieved relative to the untreated lower teeth. Treatment for the lower teeth may then proceed after the upper teeth have been whitened to the degree
5 desired by the consumer.

After the custom fitted retainer 2 is taken out of the mouth, the retainer 2 should be rinsed and the teeth should be brushed with a fluoride toothpaste. When not in use, the custom fitted
10 retainer 2 should be kept in its storage case 22.

While this invention has been described as having preferred design, it is understood that it is capable of further modification, uses and/or adaptations of the invention following in general
15 the principle of the invention and including such departures from the present disclosure as come within known or customary practice in the art to which the invention pertains, and as may be applied to the essential features set forth, and fall within
20 the scope of the invention or the limits of the appended claims.

-13-

I claim:

1. A method for whitening the teeth of a person, comprising the steps of:

- 5 a) providing a retainer made of a plastic material adapted to be moldable when heated for conforming to the shape of one of the upper and lower teeth of the person;
- b) heating the retainer until soft and
10 moldable without losing its basic shape;
- c) fitting the retainer around one of the upper and lower teeth;
- d) applying a layer of tooth whitening composition inside the retainer;
- 15 e) wearing the loaded retainer for several hours each day until the teeth to be whitened have become whiter;
- f) replacing the tooth whitening composition every 1-2 hours;
- 20 g) repeating the above steps with another retainer for the other of the lower and upper teeth.

2. A method as in Claim 1, and further comprising the step:

-14-

a) heating the retainer with boiling water.

3. A method as in Claim 1, and further comprising the step of:

5 a) heating the retainer with boiling water for approximately 5 seconds.

4. A method as in Claim 2, and further comprising the step of:

10 a) waving the retainer while completely submerged in boiling water.

5. A method as in Claim 1, and further comprising the step of:

a) biting firmly into the retainer immediately after said heating step;

15 b) pressing the tongue against the back of the upper teeth;

c) sucking out any air from the first retainer; and

20 d) using the fingers to mold the retainer around the front of one of the upper and lower teeth.

6. A method for whitening teeth as in Claim 5 and further comprising the step of:

-15-

a) keeping the retainer in the mouth for
30 seconds.

7. A method for whitening teeth as in Claim 6
and further comprising the step of:

5 a) removing the retainer from the mouth;
and

b) dipping the retainer in cold water.

8. A method as in Claim 7, and further
comprising the step of:

10 a) trimming the retainer of any excess
material.

9. A method as in Claim 8, and further
comprising the step of:

15 a) applying a layer of the tooth
whitening composition along an inside front surface
of the retainer.

10. A method for whitening teeth as in Claim 9
and further comprising the step of:

20 a) wearing the loaded retainer
approximately 5-18 hours per day.

11. A method as in Claim 9, and further
comprising the step of:

-16-

a) brushing the teeth before placing the loaded retainer in the mouth.

12. A method as in Claim 10, and further comprising the step of:

5 a) brushing the teeth with fluoride toothpaste after taking the loaded retainer from the mouth.

13. A system for whitening teeth of a person, comprising:

10 a) a custom fitted U-shaped retainer made of a material adapted to be moldable when heated for conforming to the shape of the upper or lower teeth of the person, said retainer being custom fitted by heating said retainer and fitting around the upper
15 or lower teeth;

b) said retainer including a front bite portion and a pair of rearwardly extending leg portions therefrom;

20 c) said member including inner and outer retaining walls and a connecting base portion for forming a trough;

d) tooth whitening composition disposed in said trough;

-17-

e) whereby when said retainer loaded with said tooth whitening composition is worn by the person, said composition comes in contact with the teeth to be whitened.

5 14. A system as in Claim 13, wherein:

a) said trough includes front inside surface; and

b) said composition is disposed on said inside surface.

10 15. A system as in Claim 13, wherein:

a) said composition comprises 10% Carbamide Peroxide.

16. A system as in Claim 13, wherein:

15 a) said composition consists of 10% Carbamide Peroxide, EDTA disodium, citric acid, Carbopol 940, Triethanolamine, glycerin, and flavors.

17. A system as in Claim 13, wherein:

20 a) said retainer has a thickness range of approximately 0.078-0.09 inch.

18. A kit for whitening the teeth of a person, comprising:

-18-

- a) a U-shaped retainer for each of the upper and lower teeth of a person, said retainer being made of a material adapted to be moldable when heated for conforming to the shape of the upper or lower teeth;
- b) said retainer including a front bite portion and rearwardly extending leg portions;
- c) said retainer including inner and outer retaining walls and a connecting base portion for forming a trough for receiving a tooth whitening composition;
- d) a dispenser for said tooth whitening composition;
- e) tooth whitening composition comprising 10% Carbamide Peroxide; and
- f) a case for said retainer.
19. A kit as in Claim 18, wherein:
- a) said composition consists of 10% Carbamide Peroxide, EDTA disodium, citric acid, Carbopol 940, Triethanolamine, glycerin, and flavors.
20. A kit as in Claim 18, wherein:

-19-

a) said retainer has a thickness range of
approximately 0.078-0.09 inch.

1/2

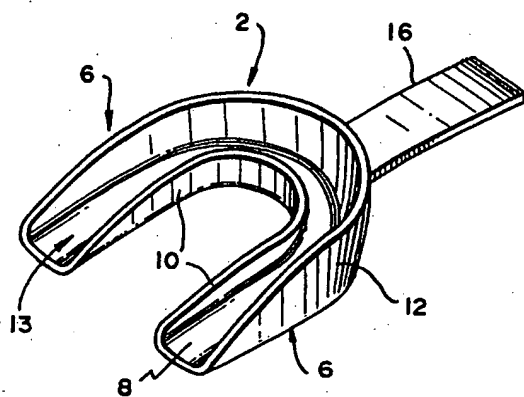


FIG. 1

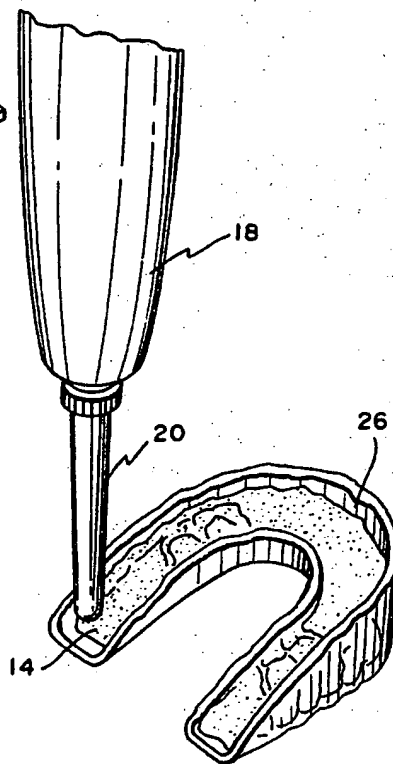


FIG. 4

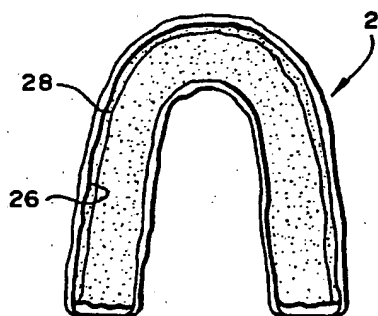
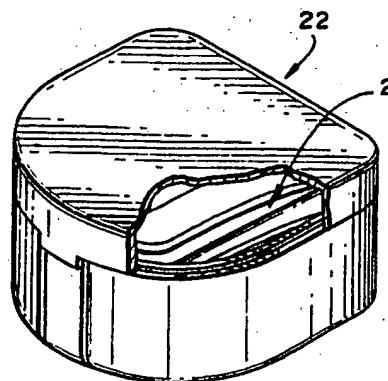


FIG. 5

FIG. 6



2/2

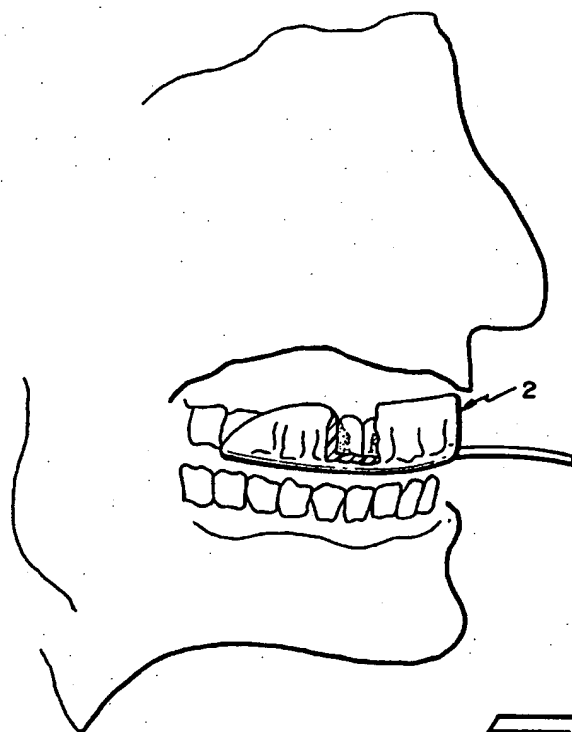


FIG. 2

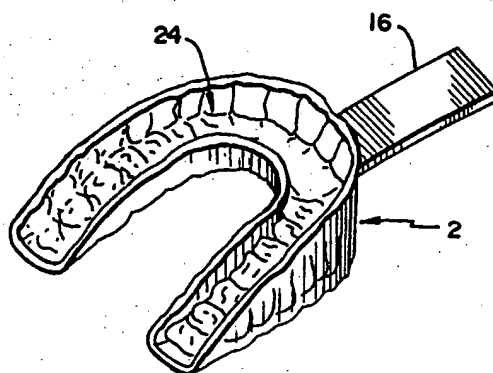
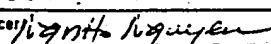


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/05556

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5); A61C 7/00 US CL ; 128, 18, 61		
II. FIELDS SEARCHED		
Minimum Documentation Searched ?		
Classification System	Classification Symbols	
U.S.	128 433/215,216,6,217.1 859,860,861,862	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
A,P	US, A, 4,944,947 (NEWMAN) 31 JULY 1991 See entire document.	
A	US, A, 2,833,278 (ROSS) 06 MAY 1958 See entire document.	
A	US, A, 3,060,935 (RIDDELL) 30 OCTOBER 1962 See entire document.	
Y	US, A, 3,379,193 (MONAGHAN) 23 APRIL 1968 See entire document.	1,2,3,9,13-15
Y	Haywood, "Nightguard Vital Bleaching" pp. 173 & 175 Clinical Research Associates, Newsletter December 1989	1,2,3,9,13-15
A	Clinical Research Associates Newsletter July 1989	
<p>* Special categories of cited documents: **</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
02 DECEMBER 1991	19 DEC 1991	
International Searching Authority	Signature of Authorized Officer	
ISA/US	 NGUYEN NGOC-HO Kerry Owens INTERNATIONAL DIVISION	

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER: _____**

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.